UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,668	09/07/2000	Jiangchun Xu	210121.484C3	2196

7590 07/01/2003

Cynthia L. Shumate
CORIXA CORPORATION
1124 Columbia Street Suite 200
Seattle, WA 98104-2048

EXAMINER
SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/656,668	XU ET AL.	
	Examiner	Art Unit	
	Monika B Sheinberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,6-8,22,65 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6-8,13,22,65 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment filed 03 April 2003

Applicants' arguments, filed 03 April 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The cancellation of claim 4 is acknowledged. Claims 3, 6-8, 13, 22, 65 and 66 are pending.

Declaration – 37 CFR 1.132

The declaration under 37 CFR 1.132 filed 03 April 2003 is insufficient to overcome the rejection of claims 3, 13, 22, 65 and 66 based upon 35 USC 101 non-statutory subject matter due to lack of utility. The instant declaration is not support by the specification for evidence of comparing ovarian normal tissue to ovarian tumor tissue. The specification indicates the polynucleotides of the instant application are "expressed at a level that is at least two fold greater than the level of expression in **normal tissues, as determined using a representative assay provided herein**"(emphasis added). However upon review of the indicated "representative assays" within the specification, pages 90-100, normal tissues described are pancreas, PBMC, skin, and bone marrow; ovarian normal tissue was free from the normal tissues utilized for the determination of overexpression as pointed to within the specification.

New Grounds of Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65 and 66 are rejected as necessitated by amendment, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claims 65 and 66 recite the limitation "oligonucleotides comprising 20-40 nucleotides that hybridize under moderately stringent conditions" that are not supported by the specification. The following exert from the specification (bridging paragraph of pp. 87-88) lacks support for the oligonucleotides consisting of 20-40 contiguous nucleotides in the amended claims 65 and 66.

> To permit hybridization under assay conditions, oligonucleotide primers and probes should comprise an oligonucleotide sequence that has at least about 60%, preferably at least about 75% and more preferably at least about 90%, identity to a portion of a polynucleotide encoding a tumor protein of the invention that is at least 10 nucleotides, and preferably at least 20 nucleotides, in length. Preferably, oligonucleotide primers and/or probes hybridize to a polynucleotide encoding a polypeptide described herein under moderately stringent conditions, as defined above. Oligonucleotide primers and/or probes which may be usefully employed in the diagnostic methods described herein preferably be at least 10-40 nucleotides in length. In a preferred embodiment, the oligonucleotide primers comprise at least 10 contiguous nucleotides, more preferably at least 15 contiguous nucleotides, of a DNA molecule having a sequence as disclosed herein.

As such, claims 65 and 66 are found to contain subject matter that is considered to be new matter. Applicants are required to point to the specific page and line numbers that provide support for amendments made to the claims.

Maintained Rejections:

Claim Rejections - 35 USC § 101/112

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.
"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 3, 6-8, 13, 22, 65 and 66 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

This rejection is maintained with respect to claims 3, 4, 6-8, 13, 22, 65 and 66 for reasons of record. Applicants argue that page 6, lines 19-28 of the specification discloses that the polynucleotides of the instant invention have a level of expression "greater than the level of expression in normal tissues" (line 28). However the rest of the phrase continues to state that the observed expression was determined "using a representative assay as provided herein" (bridging sentence between pp. 6-7). Upon review of the indicated "representative assays" within the specification, pages 90-100, normal tissues described are pancreas, PBMC, skin, and bone marrow; ovarian normal tissue was free from the normal tissues utilized for the determination of overexpression as pointed to within the specification. Thus comparison of significant levels of expression between normal ovarian and tumorous ovarian is lacking from the disclosure.

Applicants argue the provided evidence of the Declaration of Dr. Steve Fling (filed 27 September 2002). As stated in the previous office action, the Declaration only notions the comparison to normal ovarian tissue (Declaration, p. 2, line 17) with no further evidence of significant expression level difference between the two. If the sequence is expressed in normal

ovarian tissue, the comparison between the expression levels of the tumorous ovarian tissue and normal ovarian tissue is not disclosed except the indication that one was done. This is not sufficient to provide diagnostic utility of the basis of SEQ ID NO: 198's ovary-tumor associated expression profile. In addition, the Declaration is found not have support in the specification of normal ovarian tissue being included within the normal tissue samples compared to ovarian tumorous samples.

Applicants argue that the Declaration of Dr. Steve Fling (filed 03 April 2003) provides the evidence of significant over-expression levels of SEQ ID NO: 198 in view of three normal ovarian tissue samples. As stated above, the Declaration is found not have support in the specification of normal ovarian tissue being included within the normal tissue samples compared to ovarian tumorous samples. The specification indicates the polynucleotides of the instant application are "expressed at a level that is at least two fold greater than the level of expression in **normal tissues, as determined using a representative assay provided herein**"(emphasis added). However upon review of the indicated "representative assays" within the specification, pages 90-100, normal tissues described are pancreas, PBMC, skin, and bone marrow; ovarian normal tissue was free from the normal tissues utilized for the determination of over-expression as pointed to within the specification.

Applicants further argue that the expression of any 50 contiguous nucleotides of SEQ ID NO: 198 would be over-expressed in ovarian cancer therefore useful in detection of ovarian cancer since only females would be examined. Examiner cited the accession number AI023799 which was derived from a male's spleen and liver for reasons that spleens and livers are not isolated to the male specie. The indication that 210 contiguous residues of SEQ ID NO: 198 were 100% identical was to exemplify that the claims include sequences other than the elected sequence which could not lead to a useful diagnostic in the detection of ovarian cancer. Another example can be that of a sequence derived from kidney tumors, GenBank accession number AI307373 (08-April-1999), that has 100% identity to SEQ ID NO: 198 of 204 contiguous nucleic acids.

Claims 3, 6-8, 13, 22, 65 and 66 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible

utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 6-8, 13, 22, 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained with respect to claims 3, 13, 22, 65 and 66 for reasons of record. Applicants argue that adequate description of the tumor-specific profile of SEQ IDNO: 198 has been provided to cover the genus encompassed by the claims. This is not persuasive for reason of record. The claims encompass gene sequences that extend in both directions from SEQ ID NO: 198 due to the claims language including "polynucleotides **comprising** a sequence selected from" (as for example in claim 3, preamble, lines 1-2); in addition, due to this language they encompass sequences of any magnitude and/or content that comprise at least 50 contiguous residues of SEQ ID NO: 198; and the corresponding allelic variants of sequences greater in magnitude than SEQ ID NO: 198 that have 90% local identity to the entirety of SEQ ID NO: 198 are encompassed. As stated in the record, these sequences correspond to sequences from other species, mutated fragment sequences, allelic variants, splice variants, and so forth. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph however the specification does not disclose each and every possible sequence that is encompassed by the claim. Therefore the arguments are non-persuasive to overcome the rejection based on lack of written description.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6-8, 13, 22, 65 and 66 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained with respect to claims 3, 13, 22, 65 and 66 for reasons of record. Applicants argue that the term "comprising" is well-established thus the "clear language of the claims include the sequences recited in the Markush Groups and other additional, unrecited elements" (response, p. 10, 1st paragraph). This not found to be persuasive due to the claims requiring the selection of a sequence of any magnitude and content that includes as little as 50 contiguous residues of SEQ ID NO: 198, and/or sequences that can extend at variable length in both directions from the elected sequence or at least 90% similar to the entirety; all of which the parameters of which are not defined in a clear manner. Therefore, the arguments are non-persuasive to overcome the rejection.

Please Note that although the amendments to claims 65 and 66 have overcome the 35 USC § 102 of record, claims 65 and 66 are rejected under 35 USC § 112- NEW MATTER as described above. In the case that applicants amend the claims to fall within the scope of the specification, please be reminded that the 35 USC § 102 prior art of record may be re-applied if the claims are encompassed by the references: US Patents 5,585,232 (Farr; 17-Dec-1996) and 5,589,337 (Farr, 31-Dec-1996).

Conclusion

- Claims 65 and 66 are rejected as necessitated by amendment, under 35 U.S.C. 112, first paragraph –new matter.
- Claims 3, 6-8, 13, 22, 65 and 66 are rejected under 35 U.S.C. § 101/112.
- Claims 3, 4, 6-8, 13, 22, 65 and 66 are rejected under 35 U.S.C. § 112, first paragraph – lack of written description.
- Claims 3, 4, 6-8, 13, 22, 65 and 66 are rejected under 35 U.S.C. § 112, second paragraph.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Souya, can be reached at 703-308-6565. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 27, 2003

Monika B. Sheinberg
Art Unit 1634

MBS

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600